

### **REMARKS**

Claims 20-36 are pending and stand rejected. Independent claims 20, 31 and 32 are herewith amended, dependent claims 22-25 and 30 are also amended, no claims are canceled, and no new claims are added. Thus, claims 20-36 are pending continued examination on the merits.

Applicants respectfully solicit entry and favorable consideration of the amendments and remarks presented herewith.

#### **Claim Rejections under 35 U.S.C. §102**

**Claims 20, 22-24, 26, and 29-36 are rejected as allegedly anticipated by the '470 patent to Hartlaub (Hartlaub).**

For this ground of rejection to successfully apply, then Hartlaub must disclose *each and every* claim limitation recited.

Applicants respectfully suggest that Hartlaub is directed only in a general sense to toward the notion of applying closed loop spinal cord stimulation (SCS) to minimize the impact of a cardiac insult and does not address expressly or inherently delivery of a biologically-active substance to a patient.

That is, Hartlaub fails to mention or even contemplate the subject matter claimed herein and thus Hartlaub fails to anticipate the claimed invention

#### **Claim Rejections under 35 U.S.C. §103**

**Claims 20-22, 26, 31, 32, and 36 are rejected as allegedly unpatentable over the '428 patent to Obel et al. (Obel) in view of the '917 patent to Cammilli et al. (Cammilli).<sup>1</sup>**

**Claims 20, 22-26, 31, 32, and 36 are rejected as allegedly unpatentable over the '377 patent to Sweeney et al. (Sweeney) in view of Cammilli.**

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<sup>1</sup> Applicants note that at page 5 of the non-final Office Action a citation to Sweeney et al. ('377 patent?) appears and have treated same as an inadvertent typographical error in that it seems Cammilli was the intended citation (in combination with Obel).

**Claims 20, 22-24, 26-28, and 31-36 are rejected as allegedly unpatentable over the '577 published European patent application to Holmstrom et al. (Holmstrom) in view of Cammilli.**

Since all three grounds of rejection are founded or based upon Cammilli, Applicants respectfully assert that the rejections are flawed (i.e., they each fail to constitute a *prima facie* obviousness rejection).

Applicants assert that Cammilli is completely devoid of any suggestion, teaching or disclosure tending to motivate one of skill in the art to combine the apparatus and methods of Cammilli with any of Obel, Sweeney, and Holmstrom.

The Abstract portion of Cammilli informs the focus of the reference:

The invention provides an automatic implantable defibrillator with the following essential characteristics: a) reliable recognition of a ventricular fibrillation state by noting mechanical ventricular systole noise and taking action if absent; b) effecting defibrillation not by electrical pulses fed to the heart but by a bolus of medicaments (or solutions under particular physical conditions, such as a cold bolus at 30.degree. C.) fed by a hydraulic system into the coronary sinus by a retrograde path to obtain an artificial circulation so as to rapidly pervade the coronary circuit. The symbol A.I.Ph.D. (Automatic Implantable Pharmacological Defibrillator) is proposed (D.A.I.F., Defibrillatore Automatico Impiantabile Farmacologico, in Italian).

Thus, Cammilli deals merely with pacing-level energy delivery to the myocardium and retrograde delivery of (cold) fluid in an attempt to perfuse the coronary circuit. Applicants suggest that Cammilli *teaches* away from the claimed subject matter in that Cammilli attempt to defibrillate via the proposed fluid delivery and does not provide any prophylactic therapy via neuromodulation. Furthermore, Cammilli does not provide a close-loop control system employing combinations of therapy for an anticipated cardiac insult such as an infarct or deleterious remodeling due to advancing heart failure.

The application clearly is directed to such insults as can be appreciated with reference to page 6 (at lines 26-30) of the application as-filed:

Thus, as used in the instant application, the phrase "cardiac insult" is intended to include, but is not limited to, damage or mechanical, chemical, or electrical impairment of cardiac tissue due to conditions such as heart failure, ventricular tachycardia, supraventricular tachycardia, ischemia, imbalance of autonomic tone, or the like.

Furthermore, the following passage, from page 9, lines 13-15 of the instant application, is the only recitation Applicants could locate within the application (searching for the root "defibrill"):

This housing may optionally include a pacing and/or cardioverter/defibrillator stimulation circuit for generating cardiac stimulation signals to the heart 107 using one or more leads 109, as is known in the art.

Furthermore, neither Sweeney nor Cammilli even employ the term "failure" (much less "heart failure," "infarct," "ischemia"). Thus, it appears as though the Examiner has utilized impermissible hindsight to attempt to collect diverse references to fashion a facially-attractive set of obviousness rejections. Without the benefit of the presently claimed subject matter, Applicants respectfully suggest that the claimed combination cannot be found in the relevant prior art and certainly not in the references applied hereinabove.

### **Conclusion**

Applicants suggest that the claimed invention is sufficiently patentably distinct from the applied references and as such allowable over the art of record. Applicants respectfully request that the Examiner issue a Notice of Allowance so the claimed invention can pass to timely issuance as U.S. Letters Patent.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

Hill et al. by their attorney

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